

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES  
Antimicrobials Division

August 21, 2003

**MEMORANDUM:**

**Subject:** Efficacy Review EPA Reign. 1677-129 Oxonian Active  
DP Barcode 289827  
Case No. 015834

**From:** Nancy Whyte, Microbiologist *NW*  
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**Thru:** Emily Mitchell, M.S., Team Leader *Emily Mitchell 8/25/03*  
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**Thru:** Michele E. Wingfield, Chief  
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**Applicant:** ECOLAB, Inc.  
370 N. Wabash Street  
St. Paul, MN 55102

**Formulation Label:**

<u>Active Ingredient(s)</u>	<u>%/wt</u>
Hydrogen peroxide.....	27.5%
Peroxyacetic acid.....	5.8%
Other ingredients.....	66.7%
Total.....	100.0%

**I. Background:**

The product, Oxonia Active (EPA Reg. No. 1677-129), is an EPA-approved sanitizing

rinse for precleaned or new bottled water containers. The product is also approved for other uses (e.g., as a disinfectant, as a non-food contact sanitizer) on hard, non-porous surfaces in household, institutional, industrial, commercial, animal care, and hospital or medical environments. The label claims that the product is effective "as a sanitizer when solution is prepared in water of up to 500 ppm hardness as  $\text{CaCO}_3$ ." The active ingredients of the product are listed as hydrogen peroxide (27.5%) and peroxyacetic acid (5.8 %); the product contains no halides.

This data package is a re-submission of information in response to an EPA letter dated February 13, 2003, and corrects pages 4, 19, and 44 of the laboratory report identified as Study Number 0200017. The applicant apparently requested an update of their label to reflect use of the product to sanitize precleaned or new returnable or non-returnable bottled water containers at a lower rinse for precleaned or new bottled water containers at a temperature of 40–60°C for a longer contact time against *Staphylococcus aureus*, *Escherichia coli*, and *Pseudomonas aeruginosa*. The study to support this claim was conducted at Ecolab Inc., Research and Development Center, located at 840 Sibley Memorial Highway, Mendota Heights, MN 55118.

The last accepted label contained one set of directions for use of the product to sanitize bottled water containers; the applicant's amendment seeks to add an alternate set: This data package contained EPA Form 8570-4 (Confidential Statement of Formula), one study (MRID No. 458900-01), a Statement of No Data Confidentiality Claims for the study, and the proposed label.

Treatment	Use Solution	Concentration	Contact Time & Temperature	Effective Against
Currently Approved Procedure	10-40 oz/ 8 gal.	1.0-4.0% v/v	>7 seconds at 40-60° C	<i>Staphylococcus aureus</i> , <i>Escherichia coli</i> , <i>Salmonella choleraesuis</i> <i>Pediococcus damnosus</i> , <i>Lactobacillus</i> <i>malefermentans</i> , and <i>Saccharomyces cerevisiae</i>
Proposed Additional Procedure	3.0-10 oz/ 3 gallon	0.3%-1.0% v/v	>20 seconds/ 40-60°	<i>Staphylococcus aureus</i> , <i>Escherichia coli</i> , and <i>Pseudomonas aeruginosa</i>

**Note:** DynCorp obtained a copy of the last accepted label (dated April 30, 2002) from the Internet.

**Note:** EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

## II. Use Directions:

The product is designed to be used to sanitize precleaned or new returnable or non-returnable bottled water containers. Directions on the proposed label provided the following information regarding preparation and use of the product as a beverage container sanitizer: Pre-clean surfaces. Prepare a use solution of 0.3% to 1.0% by mixing 3-10 oz. of the product

per 8 gallons of water. Apply the use solution to container surfaces at a temperature of 40-60°C for at least 20 seconds. Drain thoroughly. Rinse interior container surfaces with a disinfected water rinse free of pathogenic bacteria.

### III Agency Standards for Proposed Change:

#### Sanitizing Rinses for Previously Cleaned Food Contact Surfaces

Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different batches, one of which is at least 60 days old, against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x 10<sup>6</sup>/mL for percent reductions to be considered valid. The minimum concentration of the product which provides the results required above is the minimum effective concentration. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution from the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances. The above Agency standards are presented in DIS/TSS-4 and -17, as well as the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product already registered as a sanitizing rinse for previously cleaned food contact surfaces. Confirmatory test standards would apply. For sanitizing rinses for previously cleaned food contact surfaces, 2 product samples, representing 2 different batches, must be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.999% in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, according to information in the above AOAC test method itself, counts on number controls for the product should fall between 75 and 125 x 10<sup>6</sup>/mL for percent reductions to be considered valid.

Bottled water products must comply with U.S. Food and Drug Administration regulations. Certain regulations for processing and bottling of bottled drinking water are set forth in 21 CFR Part 129, and include minimum times and intensities for sanitizing surfaces using chemical sanitizers. Specifically, chemical sanitizers should be equivalent in bactericidal action to a 2-minute exposure of 50 ppm of available chlorine at 57°F when used as an immersion or circulating solution [see 21 CFR 129.80(d)(3)]. No precise contact time for chemical sanitizers is provided in this CFR section. The regulations also permit the use of a disinfected water rinse free of pathogenic bacteria to rinse sanitized containers prior to filling [see 21 CFR 129.80(d)(5)].

#### IV Comments on Summary of Studies:

MRID 458900-01 "Oxonia Active Food Contact Surface Sanitizing Efficacy at 40°C," by Matthew J. Finley. Study conducted at Ecolab Inc. Study completion date – January 29, 2003. Amended report date – March 18, 2003. Study ID Number 0200017.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11229), and *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. J090221, 10548-71-1, and 10548-69-1) of the product, Oxonia Active, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16<sup>th</sup> Edition, 1995. At least one product lot (Lot No. J099221) was at least 60 days old at the time of testing. A 0.3% use solution (w/w, not v/v) was prepared by diluting the product to 178 ppm peroxyacetic acid in 500 ppm synthetic hard water (titrated at 510 ppm). A 99-mL aliquot of the use solution was transferred to a sterile, 250-mL Erlenmeyer flask and placed in a water bath at 40±2°C. One-mL bacterial suspension was added to each flask. *Pseudomonas aeruginosa* was added only to flasks containing Lot Nos. 10548-71-1 and 10548-69-1. After an exposure time of 20 seconds, one-mL aliquots of the bacterium-product mixture was transferred to 9 mL of 0.5% sodium thiosulfate. The neutralizer tubes were mixed and 1 mL and 0.1 mL were then pour-plated in quadruplicate using tryptone glucose extract agar. All plates were incubated for 48±4 hours at 37±2°C and the colonies counted. Controls included numbers control, neutralizer effectiveness, sterility, purity, and confirmation of the challenge microorganisms.

**Note:** Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

**Note:** The study report cites Subdivision G guidelines, 91-2(k)(2) as governing this study. However, that section of the Subdivision G guidelines concerns non-food contact surface sanitizers. This is apparently a typographic error. The correct citation is 91-2(l)(2).

#### Results

MRID Number	Organism	Lot No.	Average No. Surviving	Initial Count	% Reduction
			(CFU/mL)		
458900-01	<i>Escherichia coli</i>	J090221	1.0 x 10 <sup>1</sup>	1.36 x 10 <sup>8</sup>	>99.999
		10548-71-1	1.0 x 10 <sup>1</sup>	1.36 x 10 <sup>8</sup>	>99.999
		10548-69-1	1.0 x 10 <sup>1</sup>	1.36 x 10 <sup>8</sup>	>99.999
458900-01	<i>Staph. aureus</i>	J090221	<1.0 x 10 <sup>1</sup>	1.27 x 10 <sup>8</sup>	>99.999
		10548-71-1	<1.0 x 10 <sup>1</sup>	1.27 x 10 <sup>8</sup>	>99.999
		10548-69-1	<1.0 x 10 <sup>1</sup>	1.27 x 10 <sup>8</sup>	>99.999
458900-01	<i>Ps. aeruginosa</i>	10548-71-1	<1.0 x 10 <sup>1</sup>	2.30 x 10 <sup>8</sup>	>99.999
		10548-69-1	<1.0 x 10 <sup>1</sup>	2.30 x 10 <sup>8</sup>	>99.999

## V. Labeling:

1. The proposed label includes a number of changes unrelated to the applicant's request regarding new conditions for use of the product to sanitize bottled water containers. The changes clarify label information and, in some cases, note that the use of a more concentrated solution of the product is also acceptable. All proposed changes are acceptable.

## VI. Comments and Recommendations:

1. The submitted efficacy data (MRID No. 458900-01) supports the use of a 178 ppm peroxyacetic acid dilution of the product, Oxonian Active, as a sanitizing rinse on previously cleaned, hard, non-porous, food contact surfaces when tested against *Escherichia coli*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* in the presence of 500 ppm hard water for a contact time of 20 seconds. All three product lots demonstrated at least a 99.999% reduction in the three species of bacteria tested. Three product lots, including one at least 60 days old, were tested with *Escherichia coli* and *Staphylococcus aureus*. Neutralization effectiveness testing showed positive growth of the organisms. Purity controls were reported to be pure. Sterility controls showed no growth.  
**Note:** The use solution tested in the study is not the label-specified use solution. The label directions specify the use of a 0.3-1.0% (v/v) solution; however, a 0.3% (w/w) solution was tested.
2. The proposed label claims (as supported by MRID No. 458900-01) are acceptable regarding the use of a 0.3-1.0% solution (v/v) of the product, Oxonian Active, as a sanitizer of pre-cleaned or new returnable or non-returnable bottled water containers against *Escherichia coli*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* in the presence of 500 ppm hard water on hard, non-porous surfaces for a contact time of 20 seconds.